

REMARKS

A final Office Action mailed January 6, 2005 has been received and carefully reviewed. Claims 1-35 are pending. Claims 1, 6, 14, 19, 24, 30 have been amended. Reconsideration of the application as amended and withdrawal of the finality of the rejections are respectfully requested in view of the amendments to the claims and the following remarks.

The Examiner raised a new objection to the drawings with regard to a feature recited in original claim 2. New Fig. 3C is provided that obviates the objection to claim 2. The specification has been amended to reflect the addition of Fig. 3C. The amendment to the specification at page 11, line 8 repeats the paragraph from the original specification found at page 3, line 15. No new matter has been added.

Claims 1, 3, 6, 8, 11-14, 16, 19, 21, 30, 31, and 33 stand rejected under 35 U.S.C. § 102(b) as being anticipated by *Helland et al.* (of record).

To anticipate a claim, the asserted reference must teach every element of the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. All claim elements and their limitations must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

Claims 1, 6, 14, 19, 24, and 30 of Applicant's invention, for example, are directed to a cardiac lead including a pacing electrode comprising an active fixation arrangement. A fluoropolymer coating or sleeve is provided on a majority of an exposed surface of the fixation arrangement.

In contrast to Applicant's invention, *Helland* does not teach or suggest a coating or sleeve provided on a majority of the exposed surface of the fixation arrangement. *Helland* discloses a bipolar active fixation lead having a helix 44 defining an inner electrode 46, an intermediate insulator 48, and an outer electrode 50, as shown in Figures 3-5 of *Helland*. The outer and central electrodes 50, 46 operate as a bipolar electrode pair. As can be seen in Figures

3-5 of *Helland*, the intermediate insulator 48 does not cover a majority of the exposed surface of the fixation member. The inner 46 and outer 50 electrodes form the majority of the exposed surface of *Helland*'s fixation member and these elements are not covered by the insulator.

Because *Helland* does not disclose all of the elements recited in amended claims 1, 6, 14, 19, 24, and 30, Applicant's invention is patentable over *Helland*.

Claims 2, 4, 7, 9, 15, 17, 20, 22, 32, and 34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Helland* in view of *Carson* (of record).

To establish *prima facie* obviousness of Applicant's claimed invention, the Examiner has the burden of proving that three basic criteria are met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. All three of these criteria must be met in order to support a finding of *prima facie* obviousness of a claimed invention (see, e.g., MPEP § 2142).

As described above, *Helland* does not teach or suggest a coating or sleeve provided on a majority of the exposed surface of the fixation arrangement. *Carson* does not supply this element. *Carson* describes a defibrillation coil enclosed in a continuous sheath of open-celled porous plastic. See *Carson*, column 2, lines 39-41. A defibrillation coil enclosed in a sheath is far removed from the coated helical fixation arrangement of Applicant's invention. Because the references cited by the Examiner do not teach or suggest all of the claim limitations, Applicant's invention is patentable over the combination of *Helland* and *Carson*.

Further, *Carson* expressly teaches that portions of lead 12 not covered by the sheath include the distal pacing electrode 20, which is shown to include a

helix or tine fixation element. See *Carson*, column 4, lines 34-36. It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). The references cited by the Examiner fail to suggest the desirability of the combination and provide no motivation to make the asserted combination as required to establish a *prima facie* case of obviousness. For at least these reasons, claims 2, 4, 7, 9, 15, 17, 20, 22, 32 and 34 are patentable over the combination of *Helland* and *Carson*.

Claims 5, 10, 18, 23, and 35 stand rejected under U.S.C. § 103(a) as being unpatentable over *Helland* in view of *Stokes*. Claims 24, 25 and 27 stand rejected under §103(a) as being unpatentable over *Dutcher et al.* in view of *Helland*. Claims 26-28 stand newly rejected over *Dutcher* in view of *Helland* as applied to claim 24 and in further view of *Carson*. Claim 29 stands rejected under §103(a) over *Dutcher* in view of *Helland* as applied to claim 24 and in further view of *Stokes* (of record).

Each of the above-listed obviousness rejections relies on the teaching of *Helland*. Applicant asserts that these references, when combined with *Helland*, fail to render the claims listed above unpatentable. A *prima facie* case of obviousness requires that the asserted references teach or suggest all of the claim elements. In each of the combinations asserted above, none of the asserted references (*Helland*, *Carson*, *Stokes*, *Dutcher*) teaches or suggests, for example, a fixation arrangement having a fluoropolymer coating or sleeve provided on a majority of an exposed surface of the fixation arrangement.

Neither *Helland* nor *Carson* describes this element for the reasons discussed above. *Stokes* describes a pacing lead that has a bore for passage of a drug to the stimulation and fixation site. The fixation element in *Stokes* does not have a coating or sleeve. *Dutcher* describes an epicardial pacing lead with a stylet controlled helical fixation screw for attaching the pacing lead to the cardiac tissue. The fixation screw of *Dutcher* does not have a coating or sleeve.

Because, for each rejection made by the Examiner, the cited references do not teach or suggest all of the claim limitations of Applicant's invention, claims 5, 10, 18, 23-29, and 35 are patentable over the asserted combinations.

It is believed that the pending claims as amended are in condition for allowance and removal of the finality of the rejection is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if there are any questions regarding the above new claims or if prosecution of this application may be assisted thereby.

Respectfully submitted,
Crawford Maunu PLLC
1270 Northland Drive, Suite 390
St. Paul, MN 55120
(651) 686-6633 x104

Date: March 7, 2005

By: 

Mark A. Hollingsworth
Reg. No. 38,491

MAH/ksw

Attachments:

Replacement Drawings, Figures 3A-3C (1 sheet).

PTO-Form-1449 1/29/2004 (1 sheet).

AMENDMENTS TO THE DRAWINGS

Please enter the attached replacement sheet having original Figures 3A, 3B and new Figure 3C. No changes have been made to Figures 3A and 3B, and no new matter has been added.